

510(k) Summary
Royal Oak Medical Devices
Helena System

APR 21 2011

Premarket Notification

SUBMITTED BY	Royal Oak Medical Devices 39533 Woodward Avenue Bloomfield Hills, MI 48304
ESTABLISHMENT REGISTRATION NUMBER	Pending
OWNER/OPERATOR NUMBER	Pending
CONTACT PERSON	Matthew Kroll Vice President of Technical Services Royal Oak Medical Devices Phone: 248-628-2830 Fax: 248-969-8263
SUBMISSION PREPARED BY	Lisa Peterson QA Consulting, Inc. Phone: 512-507-0746
DATE PREPARED	March 17, 2011
CLASSIFICATION NAME	Intervertebral Body Fusion Device
DEVICE CLASS	Class II
REGULATION NUMBER	888.3080 (Product Code: MAX)
COMMON NAME	Intervertebral Fusion Device with Bone Graft, Lumbar
PROPRIETARY NAME	Helena System
IDENTIFICATION OF PREDICATE DEVICE(S)	Predicate devices include various cleared interbody fusion systems: <ul style="list-style-type: none">- RAY® Threaded Fusion Cage (P950019)- Lumbar I/F Cage (P960025)- Eminent Spine System (K090064)- SpineSmith Cynch System (K090376)- BAK Vista (P950002)

DEVICE DESCRIPTION

The Helena System will be offered in various device configurations based on surgical approach and patient anatomy, and consist of:

Lumbar interbody fusion device(s), which may be implanted

- bi-laterally via a posterior (PLIF) approach;
- as a single device via a transforaminal (TLIF) approach
- as a single device via an anterior (ALIF) approach; or

The Helena System implant components are made of polyether ether ketone (PEEK Optima LT1) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device.

The Helena System is implanted using a combination of device specific and universal class I instruments manufactured from stainless steel materials that conform to ASTM F899.

INDICATIONS

The Helena System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The purpose of this premarket notification is to obtain clearance to market the Helena System. The Helena System is comprised of various device configurations designed to accommodate patient anatomy and provide the surgeon with different surgical approach options.

The Helena System implant components are made of polyether ether ketone (PEEK Optima LT1) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device.

The subject system has similar technological characteristics as the predicate devices identified above. Specifically, the following characteristics support this conclusion:

- Intended for use at either one level or two contiguous levels from L2-S1 for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).
- Substantially equivalent results of non-clinical testing relative to static and dynamic testing (per ASTM F2077-03), subsidence (per ASTM F2267-04), and expulsion (per ASTM Draft Standard F-04.25.02.02)

DISCUSSION OF NON-CLINICAL TESTING

The following non-clinical tests were conducted:

- Static and dynamic compression testing, conducted in accordance with ASTM F2077-03
- Subsidence testing, conducted in accordance with ASTM F2267-04
- Expulsion testing, conducted in accordance with ASTM Draft Standard F-04.25.02.02

CONCLUSIONS

The subject and predicate device(s) share the same intended use, primary implant design and equivalent material of manufacture. The non-clinical mechanical test results demonstrate that any minor differences do not impact device performance as compared to the predicates and demonstrate that the Helena System is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Royal Oak Medical Devices
% Mr. Matthew Kroll
Vice President of Technical Services
39533 Woodward Avenue
Bloomfield Hills, Michigan 48304

APR 21 2011

Re: K110177

Trade/Device Name: Helena System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: March 21, 2011
Received: March 23, 2011

Dear Mr. Kroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

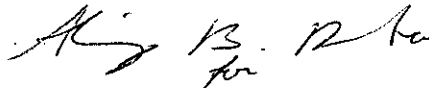
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson".

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K110177

Device Name: **Helena System**

Indications for Use:

The Helena System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110177

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